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NO. 2621 P. 2

Patent
10/785,389**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: Steven Yon et al.
Serial No.: 10/785,389
Filed: February 24, 2004
Title: Method of Manufacturing a Heat Transfer Element For In Vivo Cooling Without Undercuts
Art Unit: 3739
Examiner: Roy Dean Gibson
Docket No.: 136001
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

DECLARATION OF STEVEN A. YON
PURSUANT TO 37 CFR § 1.131

I, Steven A. Yon, Ph.D., being duly warned that willful false statements and the like are punishable by fine or imprisonment or both under 18 U.S.C. § 1001, and may jeopardize the validity of the patent application or any patent issuing thereon, state and declare as follows:

<p><u>Certificate of Facsimile Transmission</u> I hereby certify that this document and any document referenced herein has been transmitted via facsimile to the US Patent and Trademark Office at (571) 273-8300 on <u>MAY 10, 2007</u> <u>Karin L. Williams, Reg. No. 36,721</u> (Printed Name of Person Mailing Correspondence) <u>Karin L. Williams</u> (Signature)</p>
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1. All statements herein made of my own knowledge are true and statements made on information or belief are believed to be true.
2. I am over eighteen years of age, competent to make this Declaration, and have personal knowledge of the facts stated herein.
3. I am the Director of Research for Innercool Therapies, Inc. ("Applicant").
4. I hold a A.B. from the University of California, Berkeley, an Sc.M. from Brown University, an M.S. in Aerospace Engineering from San Diego State University with an emphasis in fluid mechanics and aerodynamics and a Ph.D. in Applied Mechanics at the University of California, San Diego.
5. I am familiar with the level of skill of those in the art of biomedical engineering of medical devices for intravascular temperature control of a patient on February 24, 2004, which I am informed is the filing date of the above-referenced patent application.
6. I have read and am familiar with the contents of the above-referenced patent application. I have read the Office Action mailed by the United States Patent and Trademark Office in connection with this application on November 17, 2006. I understand that pending Claims 1-9 have been rejected based upon the alleged teachings of commonly-assigned US Patent 6,478,812 (Dobak '812).

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I understand the facts to be essentially the following:

- A) The invention as recited in independent Claim 1 (the only pending independent claim) includes "a heat transfer device for intravascular temperature control of a patient, comprising: a flexible layer of a substantially conductive material, the flexible layer having in part the shape of a helical groove, and *shaped and configured such that the flexible layer lacks an undercut and may be removed from a multi-part mold*, wherein the heat transfer device includes at least two heat transfer segments separated by an articulating joint, wherein each heat transfer segment has a flexible layer.
- B) The 102(e) rejection based upon Dobak '812 indicates that Dobak discloses all elements of the claims "under the assumption by the examiner that the flexible layer of claim 1 lacks an undercut and could, therefore, be removed from a multi-part mold" (but "it is unclear from Figure 2 if the lack of an undercut exists").

7. I believe the assumption as to the teachings of Dobak '812, described above, is incorrect. One of ordinary skill in the art would have understood that Dobak '812 (and related Dobak patents that include the same drawing as Figure 2 of Dobak '812) does include an undercut and therefore could not be easily removed from a two-part mold.

8. In summary, as of the filing date of the present application, those of skill in the art of biomedical engineering would have understood that Dobak '812 illustrates a heat transfer device having an undercut.

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9. The undersigned, being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any registration resulting therefrom, declares that the facts set forth in this declaration are true; and all statements made of his own knowledge are true and all statements made on information and belief are believed to be true.



Steven A. Yon, Ph.D.
Director of Research
Innercool Therapies

05/10/07
Date